

510(k) Summary
Accel Spine Picasso II MIS Spinal System
Premarket Notification

APR 14 2014

SUBMITTED BY	Accel Spine 14901 Quorum Dr. Ste. 125 Dallas, TX 75254
ESTABLISHMENT REGISTRATION NUMBER	3009051471
OWNER/OPERATOR NUMBER	10035914
CONTACT PERSON	Lisa Peterson Kaedon Consulting, LLC 14001 Hunters Pass Austin, TX 78734 512-507-0746 (phone) 512-266-3364 (fax)
DATE PREPARED	April 11, 2014
CLASSIFICATION NAME	Orthosis, spinal pedicle fixation, for degenerative disc disease (NKB) Spondylolisthesis Spinal Fixation, Spinal Pedicle Fixation (MNI, MNH)
DEVICE CLASS	Class III
REGULATION NUMBER	888.3070 (Product Code NKB, MNI, MNH)
COMMON NAME	Pedicle Screw Spinal System
PROPRIETARY NAME	Picasso II MIS Spinal System
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include the following systems: <ul style="list-style-type: none">- Accel Spine: Picasso MIS Spinal System (K120714)- Accel Spine: Raphael System (K132365)

DEVICE DESCRIPTION

The Picasso II MIS Spinal System is comprised of percutaneous cannulated poly axial screws, a set screw and rods designed to allow for minimally invasive surgery. The screw diameters are 5.5mm, 6.5mm and 7.5mm. The screw length ranges from 30mm to 60mm in 5mm increments.

The Picasso II system will utilize Ø6.0mm MIS rods. Straight and curved rods are provided with the subject system. Straight rods are available in 35mm-600mm lengths, and curved rods are available in 35mm-150mm lengths.

The implant components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. The device specific instrumentation intended for patient contact is manufactured from stainless steel materials that conform to ASTM F899.

INDICATIONS

The Picasso II MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the Picasso II MIS Spinal System can be used in an open approach and a percutaneous approach with MIS instrumentation. The Picasso II MIS Spinal System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the Picasso II MIS Spinal System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this Special 510(k) is to obtain clearance to market the subject device as the Picasso II MIS Spinal System. The proposed system will utilize a modified version of the percutaneous poly screw housing cleared via K120714 (Picasso MIS Spinal System), and the screw and set screw cleared as part of the Raphael System (K132365).

The fundamental scientific technology and intended use are unchanged from the legally marketed predicate Picasso MIS Spinal System.

DISCUSSION OF NON-CLINICAL TESTING

Results of the engineering analysis provided in support of this premarket notification demonstrate that the modified housing dimensions for the proposed system do not create a worst case construct as compared to the predicate. As the subject device does not create a new worst case, mechanical test results submitted in support of the predicate systems are considered applicable to the subject system.

The following non-clinical tests were conducted to confirm the results of the engineering analysis:

- Static axial grip, static torsional grip, static cantilever bending and static tulip head disassociation (nominal and extreme angle), conducted in accordance with ASTM F1798-13.

CONCLUSIONS

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. Any minor differences do not impact device performance as compared to the predicates and demonstrate that the Accel Spine Picasso II Spinal System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2014

Accel Spine
% Ms. Lisa Peterson
Kaedon Consulting, LLC
14001 Hunters Pass
Austin, Texas 78734

Re: K140219

Trade/Device Name: Picasso II MIS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: April 7, 2014
Received: April 8, 2014

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140219

Device Name
Picasso II MIS Spinal System

Indications for Use (Describe)

The Picasso II MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the Picasso II MIS Spinal System can be used in an open approach and a percutaneous approach with MIS instrumentation. The Picasso II MIS Spinal System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

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Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

James P. Bertram -S

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